In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

TRENTON GOODWIN,	*	
	*	No. 19-503V
Petitioner,	*	
	*	Special Master Christian J.
v.	*	Moran
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Filed: April 16, 2024
	*	
Respondent.	*	

Glen Howard Sturtevant, Jr., Rawls Law Group, Richmond, VA, for Petitioner; Lauren Kells, United States Dep't of Justice, Washington, DC, for Respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Trenton Goodwin alleges a human papillomavirus ("HPV") vaccine was the cause-in-fact of an incidence of transverse myelitis that he developed. The Secretary contested Mr. Goodwin's allegation. Both Mr. Goodwin and the Secretary retained experts. The experts disputed several aspects of the case but this decision resolves only whether the timing between the vaccination and the onset of neurologic problems is appropriate.

Mr. Goodwin has failed to show the latency between the vaccination and the onset of his transverse myelitis is compatible with a finding that the vaccination

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

caused the transverse myelitis. Simply put, an interval of 68 days exceeds the expected amount of time. Because Mr. Goodwin does not prevail on the timing element, he is not entitled to compensation.

I. Facts

Mr. Goodwin was born in 2004. Exhibit 3. He received various vaccinations throughout his life, starting with a diphtheria-tetanus-acellular pertussis vaccine in 2004 when he was an infant. Id. Mr. Goodwin received the allegedly causal HPV vaccine on March 22, 2018. Exhibit 3 at 1; Exhibit 6 at 2. Although he received other vaccines on that date, Mr. Goodwin's claim rests upon the HPV vaccine.

Mr. Goodwin went to an emergency room for various problems, including mottled extremities, on May 30, 2018. His mother reported that the problems started "today." Exhibit 7 at 64. Mr. Goodwin was hospitalized.

While in the hospital, Mr. Goodwin underwent various tests including an MRI. The MRI was consistent with transverse myelitis. Exhibit 7 at 99. The neurologists the parties retained agreed that transverse myelitis is an appropriate diagnosis and that the initial manifestation was on May 30, 2018. See Exhibit 11 (Dr. Steinman's report) at 15, Exhibit A (Dr. Ghosh's report) at 7. The interval between March 21, 2018 (the date of vaccination) and May 30, 2018 (onset of symptoms) is 68 days.

Mr. Goodwin's course of transverse myelitis is not relevant to deciding the pending motion. For details, see Pet., filed Apr. 4, 2019 and Resp't's Rep., filed Sep. 6, 2019.

II. Procedural History

Mr. Goodwin's mother Sheri McCluskey initiated the litigation by filing a petition on April 4, 2019 when Mr. Goodwin was still a minor[2]. Mr. Goodwin filed his medical records on various dates.

[2] The caption was amended on March 27, 2024 after Mr. Goodwin reached the age of majority. This decision refers to Mr. Goodwin, although most steps in the litigation were carried out by Ms. McCluskey on Mr. Goodwin's behalf.

The Secretary disputed Mr. Goodwin's entitlement to compensation. Resp't's Rep. The Secretary questioned whether the timing was appropriate. Id. at 8.

The parties retained experts. Mr. Goodwin retained Lawrence Steinman, who has often testified for petitioners in the Vaccine Program. Dr. Steinman wrote four reports. Exhibits 11, 27, 29, and 37. Dr. Steinman proposed that the HPV vaccination can cause transverse myelitis via molecular mimicry. He also maintained the Menge case series demonstrates the timing fits Mr. Goodwin's case.

The Secretary retained two experts: Partha Ghosh, a pediatric neurologist, and S. Mark Tompkins, who has earned a PhD in immunology but is not a medical doctor. Each wrote three reports. Dr. Ghosh's reports are Exhibits A, AA, and JJ. Dr. Tompkins's reports are Exhibits K, CC, and LL. They disputed whether the HPV vaccine causes transverse myelitis. For example, Dr. Ghosh cited an epidemiologic study, Baxter.

After these reports were filed, a status conference was held. A primary question was whether 68 days is an appropriate interval. The parties agreed to submit briefs. Order, issued May 24, 2022.

Both parties advocated. Mr. Goodwin filed his primary brief on July 25, 2022, and his reply on December 21, 2022. In between, the Secretary submitted his brief on September 23, 2022. With the submission of Mr. Goodwin's reply brief, the case is ready for adjudication.

III. Standards for Adjudication

A. General

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is

too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

B. Commentary on the Timing Element

The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

For the expected temporal relationship, the timing depends upon the theory being offered. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013); Veryzer v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 344, 356 (2011), aff'd without op., 475 Fed. App'x 765 (Fed. Cir. 2012).

Although special masters should not impose hard and fast deadlines for timing, Paluck v. Sec'y of Health & Hum. Servs., 786 F.3d 1373, 1383-84 (Fed. Cir. 2015), special masters may find a proposed amount of time excessive. See, e.g., Hennessey v. Sec'y of Health & Hum. Servs., 91 Fed. Cl. 126, 142 (2010) (the expert's "overly broad" opinion on timing effectively "renders Althen's third prong a nullity"). A purpose of the timing requirement is to distinguish cases in which the onset of the disease is either too early or too late for a vaccination to have caused the illness. See Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). In considering whether a temporal interval is appropriate, special masters should distinguish a "literal meaning" from a "scientific meaning." Pafford v. Sec'y of Health & Hum. Servs., 64 Fed. Cl. 19, 29 (2005), aff'd, 451 F.3d 1352 (Fed. Cir. 2006).

IV. Analysis

The parties' briefs show only a limited amount of information is relevant to deciding the pending question. Mr. Goodwin advances (1) Dr. Steinman's opinion, (2) the Menge case series, (3) the Agmon-Levin case series, and (4) the Baxter article. In contrast, the Secretary advances (1) the opinions of his experts, Dr. Ghosh and Dr. Tompkins, (2) reports involving more than 40 people with transverse myelitis, and (3) analyses in other cases.

The analysis focuses on Dr. Steinman because Mr. Goodwin bears the burden to prove his case with preponderate evidence. Dr. Steinman relies upon the Menge case series.[3] See Exhibit 11 at 16, Exhibit 27 at 4, Exhibit 29 at 1-3 (citing White v. Sec'y of Health & Hum. Servs., No. 15-1521V, 2019 WL 7563239 (Fed. Cl. Spec. Mstr. Dec. 19, 2019)), and Exhibit 37 at 2, 6. Dr. Steinman does not unpack the steps of his theory to explain how the process of molecular mimicry could culminate in the development of transverse myelitis sixty-eight days later. See Contreras v. Sec'y of Health & Hum. Servs., No. 05-626V, 2012 WL 1441315, at *9-24 (Fed. Cl. Spec. Mstr. April 5, 2012) (discussing the sequence of steps for molecular mimicry), mot. for rev. denied in relevant part after intervening proceedings, 121 Fed. Cl. 230, 246-47 (2015), vacated on other grounds and remanded, 844 F.3d 1363 (Fed. Cir. 2017).

Dr. Ghosh and Dr. Tompkins disputed the value of the Menge case series. Dr. Ghosh and Dr. Tompkins note that the authors of the Menge article stated that they were presenting four people who received and HPV vaccine and then developed neuromyelitis optica ("NMO"). See Exhibit 25 (Menge). Dr. Ghosh and Dr. Tompkins accurately state that Mr. Goodwin did not suffer from NMO. Mr. Goodwin had transverse myelitis. Thus, they seem to reason that case reports about NMO do not inform (and cannot inform) investigation about transverse myelitis.

Dr. Steinman does not tackle head on the question of whether NMO cases can serve as a basis of comparison for transverse myelitis cases. Instead, Dr. Steinman opines that of the four cases Menge and colleagues reported, two cases could have been transverse myelitis, not NMO. Exhibit 27 at 2.

Dr. Steinman's re-diagnosis seems to stretch his abilities. Dr. Steinman did not examine the subjects in the Menge case series, and he possesses a limited

[3] Til Menge et al., Neuromyelitis Optica Following Human Papillomavirus Vaccination, 79 NEUROLOGY 285 (2012); filed as Exhibit 25.

amount of information about them. Dr. Steinman has not persuasively shown that the doctors treating these two patients erred in their diagnoses.

A more critical question is whether evidence about condition A (for example NMO) can inform an analysis about condition B (for example transverse myelitis). The Federal Circuit authorizes the use of circumstantial evidence. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Thus, special masters have often based findings regarding the appropriate temporal relationship on studies involving a disease that is different from the disease affecting a vaccinee. See Tracy v. Sec'y of Health & Hum. Servs., No. 16-213V, 2022 WL 1125281 (Fed. Cl. Spec. Mstr. Mar. 30, 2022) (when a vaccinee suffered transverse myelitis, the special master consulted studies on Guillain-Barré syndrome and acute disseminated encephalomyelitis); but see Mason v. Sec'y of Health & Hum. Servs., No. 17-1383V, 2022 WL 600415, at *25-26 (Fed. Cl. Spec. Mstr. Feb. 4, 2022) (questioning whether studies on Guillain-Barré syndrome can serve as a basis for a case involving chronic inflammatory demyelinating polyneuropathy). Whether the proposed analogy is apt depends upon a variety of factors.

Here, one factor is that the Menge case series contains, at best, a single case report in which a person may have developed transverse myelitis about five months after receiving an HPV vaccine. Case reports, however, do not show causation. Pek v. Sec'y of Health & Hum. Servs., No. 16-0736V, 2020 WL 1062959, at *19 (Fed. Cl. Spec. Mstr. Jan. 31, 2020); K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports). The Menge authors recognized that "the data currently available cannot establish a pathogenic link." Exhibit 25 (Menge) at 286.

Although Dr. Steinman advanced the Menge article as his primary support, Mr. Goodwin also puts forward an article that Dr. Steinman did not cite. Pet'r's Br. at 4-5. The Agmon-Levin group queried databases and collected 37 examples in which different vaccinations preceded the onset of transverse myelitis over approximately 39 years. Exhibit G at 1198. [4] Dr. Ghosh, who cited Agmon-Levin, emphasized that "most cases (73%) occurred during the first month, that is, within thirty (30) days, post-vaccination." Exhibit A at 8; see also Exhibit G (Agmon-Levin) at 1199. On the other hand, Mr. Goodwin emphasizes the other side of the

[4] N. Agmon-Levin et al., Transverse myelitis and vaccines: a multi-analysis. 18 LUPUS 1198 (2009); filed as Exhibit G.

coin. This "very same study also found that in 27% of transverse myelitis cases following vaccination, onset occurred more than 30 days after vaccination." Pet'r's Br. at 5.

Like Menge, Agmon-Levin is essentially a case series which carries little value. Bowling v. Sec'y of Health & Hum. Servs., No. 18-109V, 2023 WL 6846491, at *14 (Fed. Cl. Spec. Mstr. Sep. 20, 2023); Pearson v. Sec'y of Health & Hum. Servs., No. 16-9V, 2019 WL 3852633, at *9 (Fed. Cl. Spec. Mstr. July 31, 2019) (summarizing a report from an expert respondent retained).

To the extent that the Menge authors are suggesting that a neurologic disease, which they call NMO and Dr. Steinman calls transverse myelitis, was caused by an HPV vaccination given five months earlier, their suggestion is entitled to some consideration. The same is true for the Agmon-Levin authors. However, these pieces of evidence must be weighed against other evidence.

Other evidence includes the opinions from the experts. Dr. Tompkins states a "42-day risk period is widely used to determine temporal association between vaccination and an adverse event. This risk window is based upon many epidemiologic studies with infections and/or vaccinations." Exhibit CCC at 4. The larger studies, which were submitted into the record, are consistent with Dr. Tompkins's statement. Three examples are Pidcock, De Goede, and Baxter.

Pidcock. This group of researchers identified 47 children who came to the Johns Hopkins Transverse Myelitis Center over approximately four years and were diagnosed with transverse myelitis. Exhibit J at 1475.[5] Through a retrospective chart review, Pidcock and colleagues collected data regarding demographics, MRIs, cerebrospinal fluid characteristics, and functional outcomes. The researchers also identified events occurring before the onset of transverse myelitis. They found about half the cases experienced an infectious disease within about three weeks of the onset. Page 1476. They also found about one-quarter of the people who developed transverse myelitis received an immunization or allergy shot within about three weeks before the onset of neurologic symptoms. Id.

Mr. Goodwin's attempts to argue against Pidcock are generally unpersuasive. He asserts that the Pidcock "researchers only included in their study children who developed transverse myelitis within thirty days of vaccination." Pet'r's Br. at 7. This statement is not accurate. A majority (about 72%) of the

[5] F.S. Pidcock et al., Acute transverse myelitis in childhood. 68 NEUROLOGY 1474 (2007); filed as Exhibits J, Q, and RR.

subjects in the Pidcock article did not receive a vaccination in the three weeks preceding the onset of neurologic symptoms.

De Goede. This group of researchers surveyed all pediatric neurologists in the United Kingdom to report incidents of myopathy in children less than sixteen years old. Exhibit R at 480.[6] Through this process, they identified 41 cases of acute transverse myelitis. Like the Pidcock group, De Goede and colleagues reported on the children's presentation, MRI scans, treatments, and outcomes. For presentation, "27 cases had a preceding infectious illness or vaccination less than three weeks prior to presentation." Id. at 481.

Baxter. Baxter and colleagues investigated whether vaccines were associated with an increased incidence of demyelinating events including transverse myelitis. Exhibit H at 1.[7] Researchers accessed computerized medical records involving nearly 64 million vaccine doses. Id. at 5. They looked to see how often people developed transverse myelitis or acute disseminated encephalomyelitis.

The exposure interval Baxter used is important to resolving the pending motion regarding the appropriate temporal interval in Ms. McCluskey's case. Baxter wrote: "On the basis of prior studies and expert opinion, we used 2 exposure intervals: (1) 5-28 days as the most likely interval following immunization to result in a demyelination illness and (2) 2-42 days as reassurance that we are not missing an increased risk with the same type of vaccine, beyond the shorter 5- to 28- day exposure interval." Exhibit H at 4. They used "the period after the longer exposure interval, 43 days through 9 months, as the comparison interval. Nine months was chosen as the comparison interval to avoid duplicate influenza vaccines over 2 seasons." Id.

Baxter, therefore, makes explicit what is implicit in Pidcock and De Goede. Baxter, first, focused upon a period of 5-28 days as the one in which a vaccination is "most likely… to result in a demyelinating illness." Id. at 4. The broader time frame of 2-42 days was to provide reassurance. Likewise, it appears that Pidcock

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[6] Christian G.E.L. De Goede et al., Acquired transverse myelopathy in children in the United Kingdom – A 2 year prospective study. 14 EUR. J. PAEDIATR. NEUROL. 479 (2010); filed as Exhibit R.

[7] Roger Baxter et al., Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis. 63 CLIN. INFECT. DIS. 1456 (2016); manuscript version filed as Exhibit H. Because the Secretary submitted a manuscript version of the Baxter article, the page citations do not match the version as published.

and De Goede obtained information about their participants' vaccinations or infections within the preceding month.

In Baxter, the researchers were aware that some cases of transverse myelitis developed more than 42 days and less than 9 months after vaccination. Id. at 5; see also Pet'r's Br. at 6. The researchers used these cases as the basis for a "comparison interval." Exhibit H at 4. This group of comparators reflects a determination that beyond 42 days, the vaccination would not be affecting the participants. If the vaccination were still capable of causing a demyelinating disease beyond day 42, this group could not serve as a control population.

An emphasis of adverse reactions occurring within 42 days of vaccination is consistent with authorities in the Vaccine Program. For example, when the Secretary associated the flu vaccine with Guillain-Barré syndrome, which is another demyelinating disease, the Secretary conferred a presumption of causation only when the GBS started less than 42 days from the flu vaccination. 80 Fed. Reg. 45132, 45146 (July 29, 2015) (proposing Table change); See also 82 Fed. Reg. 6294 (January 19, 2017) (adopting proposed rule). One reason was that after the 1976 swine flu vaccination, there was a greater risk of developing GBS in the six weeks after the vaccination. 80 Fed. Reg. at 45146. Special masters have endorsed six weeks (or 42 days) as appropriate. See Sweeney v. Sec'y of Health & Hum. Servs., No. 13-392V, 2020 WL 1844672, at *23 (Fed. Cl. Spec. Mstr. Feb. 28, 2020); Arrendondo v. Sec'y of Health & Hum. Servs., No. 18-1782V, 2023 WL 8181138, at *31 (Fed. Cl. Spec. Mstr. Oct. 31, 2018).

Mindful that scientific standards may not always translate to the standards in civil litigation, special masters have also broadened the time period beyond 42 days. Pierson v. Sec'y of Health & Hum. Servs., No. 17-1136V, 2022 WL 322836, at *32 (Fed. Cl. Spec. Mstr. Jan. 19, 2022) (allowing as long as eight weeks); Blender v. Sec'y of Health & Hum. Servs., No. 16-1308V, 2021 WL 1096662, at *22 (Fed. Cl. Spec. Mstr. Feb. 26, 2021) (same); see also Chinea v. Sec'y of Health & Hum. Servs., 144 Fed. Cl. 378, 386 (2019) (noting that on a motion for review petitioner did not challenge the special master's finding that six to eight weeks is appropriate). Dr. Steinman, too, has sometimes taken the position that a demyelinating disease might arise within 7-8 weeks. Tracy, 2022 WL 1125281, at *21; Giannetta v. Sec'y of Health & Hum. Servs., No. 16-213V, 2017 WL 4249946, at *21 (Fed. Cl. Spec. Mstr. Sep. 1, 2017).

Yet, this broadening is not limitless. The third prong of Althen must have some meaning. Hennessey, 91 Fed. Cl. at 142. "If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur

several weeks after inoculation, then it is doubtful the vaccination is to blame." Pafford, 451 F.3d at 1358.

Special masters, therefore, have restricted the appropriate onset window. See Archer v. Sec'y of Health & Hum. Servs., No. 15-656V, 2021 WL 2666692, at *24 (Fed. Cl. Spec. Mstr. May 27, 2021) ("54 to 67 days post-vaccination for symptom onset is beyond the time period for which a medically acceptable causal timeframe can be established"); Conte v. Sec'y of Health & Hum. Servs., No. 17-403, 2020 WL 5743696, at *26 (Fed. Cl. Spec. Mstr. July 27, 2020) (stating that eight weeks is the maximum and finding 12 weeks as too long); Pearson v. Sec'y of Health & Hum. Servs., No. 16-9V, 2019 WL 3852633, at *16 (Fed. Cl. Spec. Mstr. July 31, 2019) (finding 74 days excessive and citing cases).

The Secretary cited some of these cases. Resp't's Br. at 6. However, Mr. Goodwin did not cite any case in which a special master extended the time as far as he is proposing. Instead, Mr. Goodwin argued the medical literature shows "that the timing of Mr. Goodwin's onset of symptoms of transverse myelitis occurred during the time frame within which medical science expects the injury to appear after vaccination." Pet'r's Reply at 2.

For the reasons explained above, this argument is not persuasive. The literature shows that some people developed neurologic disorders months after a vaccination. This group would constitute people whose temporal relationship between the vaccination and disease onset is "literal." Pafford, 64 Fed. Cl. at 29. Mr. Goodwin's childhood vaccinations also literally occurred before he developed transverse myelitis. But, the Federal Circuit requires the onset to occur at a time for which an inference of causation is medically acceptable.

Mr. Goodwin has not demonstrated that a medically acceptable period extends to 68 days. Therefore, Mr. Goodwin has not met his burden regarding Althen prong 3.

V. Conclusion

Without a showing on each Althen element, a petitioner cannot receive compensation. For the reasons explained above, Mr. Goodwin's transverse myelitis started so long after his HPV vaccination that an inference that the vaccination caused the transverse myelitis would not be appropriate.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for

review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master